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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/386,605	08/31/1999	CHRISTOPHER G. TAYLOR	38-21-(15757	1594

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MONSANTO COMPANY
800 N. LINDBERGH BLVD.
ATTENTION: G.P. WUELLNER, IP PARALEGAL, (E2NA)
ST. LOUIS, MO 63167

EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 11/29/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/386,605	Applicant(s) TAYLOR ET AL.	
	Examiner Georgia L. Helmer	Art Unit 1638	

-- *Th MAILING DATE of this communication app ars on the cov r sh et with the correspond nc address --*

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 12-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction/ election

1. The Office acknowledges the receipt of restriction election, Paper No. 9, filed October 9, 2001. Applicant elects Group I, claims 1-11, with traverse, stating "that it would not create an undue burden on the Examiner to conduct a search encompassing all of the claims". Applicant's traversal is unpersuasive for the following reasons: whereas a search for Group I claims might overlap with a search for Group II claims, such a search would not necessarily be coextensive and therefore would create undue burden on Examiner. Claims 1-26 are pending. Claims 12-26 are nonelected. Claims 1-11 are examined in the instant application. This restriction is made FINAL.

Specification

Information Disclosure Statement

2. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 6, is attached to the instant Office action.

Drawings

3. This application has been filed with drawings which have been approved as formal drawings by the Office draftsman.

Claim Rejections – 35 USC § 112, second paragraph.

4. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph,

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as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is to "an explant"; explant needs to be defined. Would a whole plant be an explant?

Claim 2 is to "the method of claim 1 wherein the explant is stem or hypocotyl tissue." "Hypocotyl" is unclear; how does hypocotyl differ from stem?

Claim 3 is to the method of claim 1 wherein the explant is a hypocotyl providing a cut end below the cotyledon. "Providing" is unclear; who or what is doing the providing? "The cotyledon" lacks an antecedent.

Claim 8 is to the method of claim 4 where in the transgenic root development is initiated in the inoculated hypocotyl by placing the inoculated hypocotyl regions in a media containing $\frac{1}{4}$ MS. It is unclear how the $\frac{1}{4}$ is determined. Page 7 states " $\frac{1}{4}$ strength MS mixture. Also "MS" is improper in a claim because it is an abbreviation. Applicant should spell out in the claim what this abbreviation means and thereafter use of the abbreviation is proper. Furthermore "the inoculated hypocotyl" lacks antecedence.

Claim 9 is rejected as being dependent on indefinite claim 8.

Claim 10 is rejected as being dependent on indefinite claim 9.

Claim 11 is "The method of claim 10 wherein the concentration of kanamycin in the media is no more than about 50 mg/L. "No more than" means 50 mg/L or less. "About" means that the concentration can be more than 50 mg/L. Accordingly the metes and bounds of "no more than about" are unclear.

Clarification and/or correction are required.

Claim Rejections – 35 USC §112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 1-11 are rejected under 35 USC 112, first paragraph, because the specification while being enabling for a method which includes the step of inoculation the explant with *A. rhizogenes* containing a nucleotide sequence encoding a selectable marker, wherein said selectable marker is expressed in the explant, does not reasonably provide enablement a method without the selectable marker step as described. The recited method of Claim 1, which is lacking a nucleotide sequence encoding a selective marker, is lacking an essential element. Inoculation with *Agrobacterium rhizogenes* followed by culturing in a medium without any selection step would not predictably produce plants having transgenic roots. Such a mixed population would require many plants to be screened in order to find the plant having the desired transgenic root tissue. In the absence of selection the mixed population favoring the non-transgenic tissue would be produced. See Birch, Annu. Rev. Plant Physiol. Plant Mol. Biol. 1997, 48:297-326 especially p 302, and Figure 1, p 304 (Examiner). Such screening would require undue experimentation for one skilled in the art to

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which it pertains to make and use the claimed invention as commensurate in scope with these claims.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

In fact, claim 9 recites a selectable agent, claim 10 recites kanamycin and claim 11 recites a kanamycin concentration range. Kanamycin is toxic to plants or explants which do not express a detoxification protein such as neomycin phosphotransferase II. Since the method does not require expression of any selectable marker, it is unclear how an explant, whether or not the explant has been transformed with an exogenous genetic element, is able to survive and develop transgenic roots in a medium containing kanamycin. Neither Applicant nor the state of the art provided guidance as to how transgenic roots would be selected for without a selectable marker, or how the explants would be able to overcome kanamycin toxicity, because plants are not naturally resistant to kanamycin. Accordingly, one skilled in the art cannot make and use the invention as commensurate in scope with the claims without undue experimentation.

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6. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 5 is the method of claim 3 where in the *Agrobacterium rhizogenes* is strain K599. The specification lacks sufficient evidence that the claimed biological material is either 1) reproducible, 2) known and readily available to the public, or 3) deposited in compliance with 37 CFR 1.801-1.809. If the claimed biological material was deposited under the provisions of the Budapest treaty, Applicant must provide a declaration stating that the claimed biological material was made under the provisions of the Budapest treaty in compliance with 37 CFR 1.801-1.809, and that all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the grant of the patent. Applicant's attention is directed to 37 CFR §§1.801-1.809, MPEP §§ 2402-2411.05 and In re Lundak 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985) for further information concerning the Rules and Regulation for Deposit of Biological Materials for Patent Purposes.

Claim Rejections – 35 USC §102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 6 and 8-11 are rejected under 35 U.S.C. 102 (b) as being anticipated by Tulson et al (EP 0262972 A2 published April 6, 1988)(Applicant's IDS). Re claim 1, Tulson et al teach obtaining an explant (page 5, lines 30-40), inoculating with *Agrobacterium rhizogenes* (page 5, lines 52-55), culturing (page 5, lines 52-55), and producing plants (page 6, lines 1-15). Re Claim 2 and 3, Tulson teaches obtaining an explant (page 5, lines 30-40) where the explant is a hypocotyl. Re claim 4, Tulson teaches the cut end of the hypocotyl being contacted with *Agrobacterium rhizogenes* (page 5, lines 52-55). Re claim 6, Tulson teaches obtaining an explant from a dicot (page 5, lines 30-40). Re claim 8, Tulson teaches placing the inoculated hypocotyl on a medium containing MS (page 6, lines 4-6). Applicant is reminded that use of ¼ MS is indefinite as discussed above and thereby is given no weight in this discussion. Re claim 9, Tulson teaches placing the inoculated hypocotyl on a medium containing MS and a selectable agent. (Page 6, lines 7 and 8). Re claim 10, Tulson teaches using kanamycin wherein the concentration of kanamycin in the media is 25 mg/L (page 7, lines 22-28) and 50 mg/L (page 7, lines 29-31). Accordingly, Tulson anticipated the claimed invention.

9. Claims 1, 2, 3, 4, 6 and 7 are rejected under 35 U.S.C. 102 (b) as being anticipated by Rech et al, Plant Cell Reports 8:33-36 (1989)(Examiner). Re claim 1, Rech teaches obtaining an explant (page 33), inoculating with

Agrobacterium rhizogenes (page 33), culturing (p33), and producing plants (p34). Re Claim 2 and 3, Rech teaches obtaining an explant where the explant is a hypocotyl (p33). Re claim 4, Rech teaches the cut end of the hypocotyl being contacted with Agrobacterium rhizogenes (p 33). Re claim 6 and 7, Rech teaches obtaining an explant from a dicot where the dicot is soybean (p 33). Accordingly Rech anticipated the claimed invention.

35 U.S.C. 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-4 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rech et al, Plant Cell Reports 8:33-36 (1989) as applied to claims 1-4, 6 and 7, above, and further in view of Hatamoto et al, Plant Cell Reports 9: 88-92 (1990)(Applicant's IDS). The teachings of Rech are summarized in the above paragraph. Rech does not teach $\frac{1}{4}$ MS with kanamycin as a selectable marker at a concentration of 50 mg/L. However, Rech teaches root development initiated on another culture medium containing 50 mg/L kanamycin (p33). Hatamoto teaches making transgenic plants by inoculating an explant or a dicot with Agrobacterium rhizogenes and culturing on MS medium in the presence of kanamycin selection (pp 90 and 91).

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It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use such any known plant culture medium effective for producing transgenic plants without any surprising or unexpected results. MS culture medium containing an antibiotic selectable marker such as kanamycin was notoriously well known. Accordingly, one would have been motivated to use a plant culture medium such as MS as taught by Hatamoto to culture an explant by the method of Rech with a reasonable expectation of success.

Remarks

10. No claim is allowed.

11. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Center 1 fax machines are available to receive transmissions 24 hours/day, 7 days/week. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication should be directed to Georgia Helmer whose telephone number is (703) 308-7023. The Examiner can normally be reached Monday-Friday 8:30 AM – 5:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Georgia Helmer, Ph.D.
Patent Examiner
Group Art Unit 1638
November 26, 2001



PHUONG T. BUI
PRIMARY EXAMINER